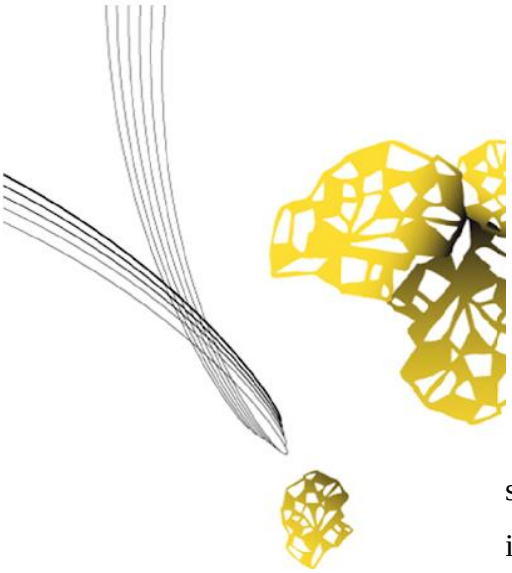

Bachelor Thesis

How important is stakeholder inclusion? A scholarly work on qualitative research to explore the importance of stakeholder inclusion in the development and implementation process of eMental health interventions.

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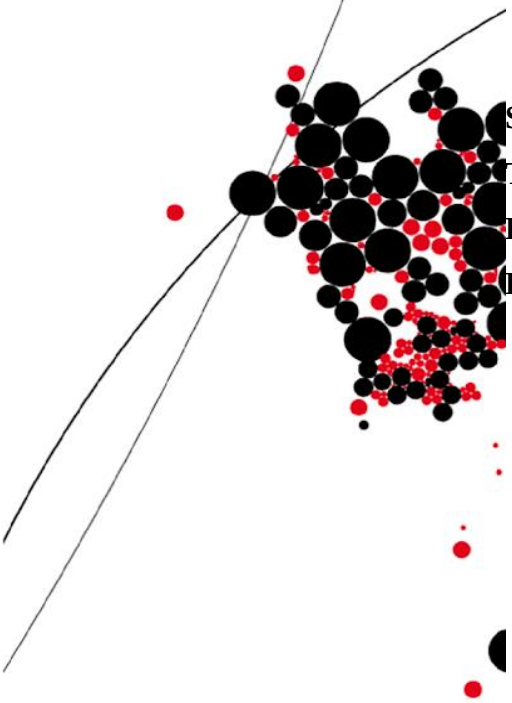

Study: Psychology
Track: Positive clinical Psychology & technology
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Abstract

This paper explored the “real world” inclusion of stakeholders in the development and implementation process of eMental health interventions. Therefore, the extent to which stakeholder inclusion is important for the design and implementation process of specific eMental Health technologies was explored. In recent decades, the supportive use of technology in the healthcare sector had become increasingly important due to an overburdened health system. One consequence was the burden on informal caregivers who looked after ill friends and relatives privately. eHealth technologies were developed to support these informal caregivers in their function and to simultaneously prevent psychological overload. These eHealth technologies offered much potential to relieve informal caregivers. However, developing an eHealth technology also involves several difficulties, such as a correct stakeholder inclusion. This paper explored how successfully implemented eMental health technologies dealt with stakeholder involvement in terms of different approaches to stakeholder inclusion as well as theories and frameworks that guide such a development process. A qualitative interview study explored different aspects of stakeholder inclusion and its guidance through a theory or framework. Therefore, seven companies with an already implemented eMental health technology for informal caregivers were interviewed. The importance of various stakeholders was explored, such as collaborations with external parties or interviewing the target group. In addition, various methods of stakeholder inclusion such as interviews, questionnaires and usability studies were examined, and the application within the development process of these specific eMental health interventions was investigated. Also, the companies were interviewed about their experiences with specific theories and frameworks that guided a stakeholder inclusion process within an intervention development. In conclusion, it can be said that stakeholder inclusion is an essential part of an eMental health intervention development. In addition, the surveyed companies did not use the full potential of the methods for stakeholder inclusion like a usability study. On top, evaluation instances were not considered by the companies during the intervention development. However, the analysed theories and frameworks do not convey the importance several aspects like stakeholder inclusion or evaluation strategies enough.

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1. Introduction

In recent years, informal health care has come to the fore due to overburdened healthcare systems (Plaß et al., 2021). This circumstance can be attributed to a demographic change, which is characterised by declining birth rates and increasing numbers in the older population (Ismail et al., 2021). The older generation particularly struggles with chronic diseases, which cause 63% of all deaths worldwide (Janssen-Heijnen et al., 2005; Durstine et al., 2013). Such chronic diseases as cardiovascular disease or cancer require intensive care for the diseased individual (Durstine et al., 2013). Based on the increasingly overburdened healthcare organisations combined with the increasing numbers of the older generation, an increasing number of nursing cases is expected (Ryan et al., 2012). This is the point when informal care becomes essential - friends or family members caring for the sick person when they can no longer care for themselves (Chiao et al., 2015). In Europe, 34.3% of all adult residents are informal caregivers (Ekman et al., 2021). However, the number of informal carers who take responsibility for their social environment is falling, as many, especially younger people, are increasingly focusing on their careers instead (Gemert-Pijnen et al., 2018). Therefore, decreasing availability of informal caregivers is expected in the future, although more than twice as many informal caregivers are needed because of the increasingly ageing society (Ryan et al., 2012). Accordingly, the informal carers who are still able to take on this responsibility are often left alone with their duties. For the informal carer, caring for a care recipient can be highly stressful, which can harm the mental health of the informal carer (Schulz & Sherwood, 2011). Caring for a chronically ill person poses major challenges for informal caregivers, as they are also responsible for the patient besides their own everyday life. This is often very time- and resource-consuming, which is why informal care can be a burden resulting in many informal caregivers suffering from psychological distress (Mello et al., 2016). Nonetheless, many chronically ill patients depend on informal caregivers, even if this places a tremendous burden on the social environment (Bastawrous, 2013). As an example, an informal caregiver provides voluntary support to family and friends that have long-lasting social or health-related needs (Tur-Sinai et al., 2020).

Since many informal caregivers suffer from their supportive function, research is increasingly being carried out on technological support options that are intended to help informal caregivers in such a way that their mental health is no longer negatively affected. This technology is used in a targeted manner to make the chronic everyday limitations of the patient more independently manageable and thus counteract the physical and, at the same time, the

psychological stress of the informal caregiver (Slev et al., 2016). The research area that deals with the development of care supporting technology is called eHealth. eHealth can be defined as the application of technology to improve healthcare, well-being, as well as health itself (Gemert-Pijnen et al., 2018). The field of eHealth offers high potential to support caregivers in providing adequate and high-quality care with the application of technology.

In the course of this work, the chances and pitfalls of eHealth and especially eMental health are considered, and the importance of a well-designed implementation is explained based on different frameworks. Based on this, the extent to which stakeholder inclusion during the design and implementation phase is decisive for implementation is derived.

1.1. eHealth & eMental Health

The application of eHealth has one goal – to facilitate and improve health care. The focus is on changing unhealthy behaviour towards a desired healthy behaviour through technology (Gemert-Pijnen et al., 2018). For this purpose, the scientific field of psychology offers the perfect complement. Psychological theories and approaches are increasingly included in the development process of eHealth technologies. The reason for this is that the psychological basis of an eHealth technology is crucial for the success of an intervention (Webb et al., 2010). The science of psychology deals specifically with explaining and changing behaviour and based on these findings, offers behaviour change techniques (Michie et al., 2013) and persuasive features (Oinas-Kukkonen & Harmuaa, 2009) for the development process. Within the framework of the intervention, these tools ensure that the technology is specifically tailored to the target group and their wishes. In addition, the implementation of the desired adherend behaviour becomes more likely (Gemert-Pijnen et al., 2018).

eHealth has a wide range of application areas. Any health-related information which is digitally provided is eHealth technology. Also, any device that promotes healthy behaviour, like a wearable or virtual reality device, fits into the category of eHealth (Gemert-Pijnen et al., 2018). In conclusion, it can be said that eHealth can assist very different areas of application to support everyday life in different aspects of the health sector.

In addition to the various possible uses of eHealth, there are also subgroups of eHealth. eMental health, for example, is a particular form of eHealth that deals solely with the care and support of mentally ill patients through technology (Ellis et al.,2021). Generally, eMental health can be defined as “mental health services and information delivered or enhanced through the internet and related technologies” (Christensen & Griffiths, 2003). The technical aids include technology-based therapy forms such as VR, internet-based programs, applications for

smartphones, informative websites, and Telehealth (Ellis et al.,2021). Regarding the further course of this work, eMental Health technologies are of particular interest, especially those which are based on a website and offer informal caregivers psychological support in dealing with stressful situations in everyday life.

1.2. Chances & Pitfalls of eHealth

The integration of eHealth technologies into the everyday life of patients can prevent many problems and disadvantages of conventional methods. For example, technical assistance is independent of time and place (Gemert-Pijnen et al., 2018). For this reason, the threshold for seeking medical help is significantly lower. As patients do not have to justify themselves to medical professionals and the technology is readily available, the support is used significantly more often than conventional help (Firet et al., 2018). Since eHealth technology should support the tasks of formal and informal caregivers as far as possible in order to relieve them of their burden, the autonomy offered to patients by eHealth plays a significant role. eHealth technologies provide patients and their caregivers with the potential of freedom and independence in dealing with medical issues and concerns (Flinsenberg, 2020). This not only has positive effects for the patients themselves, who can live out their desire for autonomy, but it can also relieve caregivers in their supporting function. On top, with less human influence on care, human errors, miscommunication, or forgetfulness can be avoided (Muthiah et al., 2019). Additionally, Duettmann and colleges (2021) found that eHealth interventions are cost-effective. The one-time acquisition costs prevent personnel and hospitalisation costs. Therefore, it can be concluded that eHealth technologies have the potential to increase both the effectiveness (Stratton et al., 2017) and the efficiency of care (Moghimi et al., 2021).

However, despite promising possibilities, there are still many potential pitfalls in the field of eHealth. Often technologies are not used in the originally designated way, thus increasing neither efficiency nor effectiveness (Gemert-Pijnen et al., 2018). The reason why eHealth technologies are less successful in implementation than expected during development can be attributed to either the design or the implementation process of the eHealth development (Greenhalgh et al., 2017). This is the case because these two steps during the development process are interconnected with each other (Gemert-Pijnen et al., 2018). An Example is poorly implemented eHealth interventions, which are the result of poor design decisions. Among others, poor design decisions are based on insufficiently involved key stakeholders, which need to be considered to identify financial or personal benefits for the target group (Gemert-Pijnen et al., 2018). On the one hand, disesteem important design decisions lead to worse behavioural

changes and, on the other hand, have an impact on the confidentiality of the technology. A wrong evaluation of the target group's technological affinity can set off a chain reaction (Ajzenman et al., 2021). More difficult handling for the target group due to a lousy investigation of their needs and wishes decreases the motivation to try out the technology and, most importantly, to integrate it into everyday life.

Another potential pitfall that is often disregarded before implementation is the transparency of responsibility (Das et al., 2015). The integration of eHealth technologies into everyday life places a certain amount of responsibility on the technology. Hence the target group must be able to see how responsible the technology is, it must be clearly defined who will be held responsible in the case of any malfunctions. In the event of a breach of trust or a faulty product design that results in the target group being unwilling to accept the eHealth intervention, this is referred to as non-adherence (Wong et al., 2020). To prevent the non-adherence of the target group, the focus must be placed on the applicability of the eHealth technology in advance, namely in the design process, so that all issues are solved at the time of the implementation.

In conclusion, the greatest pitfall of an eHealth intervention is the disregard for the interconnectedness of all components. Accordingly, any aspect of an intervention that is not thought through presents the risk that the eHealth intervention will not be properly adopted by the target group.

1.3. The meaning of stakeholders for eHealth

The involvement of stakeholders in the development and implementation process of eHealth interventions is highly relevant for avoiding the pitfalls mentioned above. A stakeholder is anyone who is influenced by eHealth technology and anyone who influences eHealth technology (Gemert-Pijnen et al., 2018). Stakeholder involvement in the development of an eHealth intervention is of high importance since the success of the intervention depends on the fulfilment of the requirements that are made by everyone who gets in touch with the intervention (Gemert-Pijnen et al., 2018). According to Nilsen and colleagues (2020), the involvement of stakeholders in the development process of an eHealth technology contributes significantly to its success (Nilsen et al., 2020). By proposing personal requirements to a potential eHealth technology, stakeholders prevent flawed design and implementation decisions. To be able to benefit from a large number of stakeholders, key stakeholders must be identified. This is done by analysing the roles and tasks of every stakeholder (Gemert-Pijnen et al., 2018). The information obtained in this way allows the identification of key stakeholders

that cover all perspectives of interest in the eHealth intervention. These key stakeholders work together with the development team of the eHealth technology during the development and the implementation phase and advise them to meet the requirements of the technology for society (Breeman et al., 2021).

To prepare for a smooth implementation, the opinions and preferences of various key stakeholders are increasingly included in the design process. The design phase can usually be divided into three different phases. First, the stakeholder requirements for eHealth technology are surveyed and analysed. Based on this, a value proposition can be created (Gemert-Pijnen et al., 2018). Then the financial aspects of the eHealth intervention are considered by creating a business model. Among others, the cost-benefit factor of eHealth technology is worked out here so that production can function sustainably, and the product can be offered at an adequate price. Here, opinions of key stakeholders are included, for example, concerning finding a fair price (Breeman et al., 2021). Finally, the design phase also includes the creation of a prototype. Here, the value propositions are converted into technical requirements. A finished prototype is then tested not only by experts but also by key stakeholders to ensure that the application runs smoothly (Gemert-Pijnen et al., 2018).

1.4. The implementation of eHealth

In the past, implementation was seen as a post-developmental phase. The reason for this was that eHealth was used more as a transmitter of technological content. Therefore, the only focus was on the adoption and acceptance of the intervention by the target group. This approach led to the development of various technologies that could not be implemented in society long term (Pieterse et al., 2018). Implementation can be defined as using evidence-based strategies that enable the targeted integration of an intervention (Leeman et al., 2017). Lokker and colleges (2015) developed a strategy that makes an eHealth intervention successful if it is readily available to the customer, proves itself through quality and is cost-efficient. Achieving these goals requires making upfront budgetary decisions that are justified by a business model (Oinas-Kukkonen, 2012). Furthermore, the entire infrastructure that is to become part of the ecosystem of eHealth technology must be analysed and prepared for implementation. To be able to fulfil all these points, selected key stakeholders from various areas are required. For example, for a successful cardiovascular eHealth solution, employers, employees, external consultants, potential end-users, HR advisors, business analysts and company doctors have been involved in the implementation process (Breeman et al., 2021). By considering this multitude of perspectives, opinions and requirements, potential errors are ruled out as best as

possible, which in the case of the cardiovascular eHealth intervention, made a significant contribution to its success. It can therefore be concluded that the success of an eHealth implementation depends on stakeholder inclusion. Also, it can be said that the implementation of an eHealth intervention is not a post-developmental phase but on the contrary, should be considered throughout the entire development process.

1.5. Implementation frameworks

In the short time that eHealth has existed, it has evolved from individual technical devices for specific groups to entire infrastructures for society as a whole. This change details numerous factors that must be included in eHealth Technology to be successful. A very crucial factor, which has not been considered in many unsuccessful eHealth interventions, is the involvement of stakeholders in both the design and the implementation process. However, ethical concerns such as security and data protection, resource management of budget, time and personnel or legal guidelines are also part of the possible pitfalls of eHealth interventions (Pieterse et al., 2018). In addition, the political and socio-cultural context in which technology is implemented plays a significant role. In addition, the internal and external structures of the implementing organisation must also be considered (Greenhalgh et al., 2017). It quickly becomes clear that the implementation of eHealth technologies has become an increasingly complex topic. To counteract this complexity, various implementation frameworks were developed to guide a smooth takeover of the eHealth technology for the target group. In the further of this paper, three frameworks will be introduced and analysed, in which guide different ways of stakeholder inclusion in the development process of eHealth interventions.

Nonadoption, Abandonment, Scale-up, Spread, and Sustainability- Framework

The so-called Nonadoption, Abandonment, Scale-up, Spread, and Sustainability-Framework (from now on referred to as NASSS) offers a contemporary approach to the implementation of eHealth technologies. The model splits the development of an eHealth intervention into six domains, which investigate different aspects of the desired product based on 13 pre-formulated questions.

Because the NASSS framework provides only 13 questions to guide the eHealth development, stakeholder inclusion is not explicitly mentioned but implicitly. The six domains that are mentioned within the framework, namely condition, technology, value proposition adopters, organisations and wider system, provide a summary of domains from which essential stakeholders can be attained for an eHealth intervention. In particular, the value proposition is examined more closely. Here, the values for the interventions are based on the condition, the

technology and the potential adopters of the technology. A certain level of stakeholder inclusion can be concluded here. Nevertheless, the domains of health/care organisation (s), wider system and continuous embedding and adaptation are not included in the value proposition. As a result, essential stakeholders and important information for the technology can be missing in the value proposition.

In summary, the NASSS Framework is a guide for the design and implementation of eHealth interventions, which specifies which aspects of an eHealth intervention must be considered for it to be successful. Nevertheless, the specification is more of a guideline that serves as an orientation. Since the framework is based on only 13 questions, the assistance is very superficial and does not guarantee success if the questions are answered.

CeHRes Roadmap

The CeHRes roadmap offers another modern approach to the development of eHealth technologies. The focus here is on a holistic development process of the technology, which, through targeted coordination between the various development steps, is intended to ensure that the technology ultimately achieves the desired effect and is smoothly accepted by the target group. Based on five different steps, good coordination between the technology, the potential users and contextual factors should be created, which ought to lead to the fulfilment of the intervention goal. The roadmap thus offers a framework that ensures that the technology is adapted to the context of the target group, which requires a participatory development process and continuous evaluation cycles. It should be particularly emphasised that the implementation has a powerful influence on all previously made decisions, through which the product is specifically prepared for implementation.

CeHRe's roadmap consists of five phases which are reiterative during the development process. As a result, the information obtained is built up on one another and adapted to one another both retrospectively and with foresight. Phase one is called contextual inquiry and focuses on the identification and analysation of stakeholders to acquire key stakeholders. In addition, the general situation of the problem is analysed. In the second phase, the value specification, the added value of the key stakeholders is identified and summarised in a value map. Demands on the technology are derived based on the values, and a business plan is also drawn up. Phase three, the design phase follows this. Here, both a low-fi and a high-fi prototype are developed and extensively tested with stakeholders, experts, and potential end-users. Attention is also paid to persuasive elements and behaviour change techniques to prepare the technology for implementation. Operationalisation is the fourth phase. Here, an

implementation plan is created based on the stakeholders, the business plan and implementation theories. Then the plan is put into action. Finally, phase five, called summative evaluation, offers to evaluate the impact and adoption of the technology in society.

The decisive difference from other implementation strategies is the strong involvement of stakeholders in the entire development process with the CeHRes roadmap. This creates an iterative and agile design approach that focusses on the participatory development process. Based on these general conditions, a complex business plan and a complex value map are required for the implementation of the roadmap (Gemert-Pijnen et al., 2018).

Consolidated Framework for Implementation Research

Furthermore, the consolidated framework for implementation research (from now on referred to as CFIR) is considered (Gemert-Pijnen et al., 2018). The framework connects five different domains to prepare the ideal implementation. In addition, it informs about different potential barriers to prevent them. The five domains refer to 40 subcategories that support planning the eHealth intervention in detail. The five domains are innovation & characteristics, outer settings, inner settings, characteristics of individuals and process.

Concerning the involvement of stakeholders in the development process, particular value is placed on the process area and, more precisely, on the engaging area. Elaborating on the opinions of leaders, champions, external change agents, key stakeholders, and innovation participants provides by far the most detailed and concrete stakeholder analysis of the frameworks mentioned in this paper. Nevertheless, the framework does not specify a structure that links knowledge from different domains with each other. As a result, the benefit of stakeholders can be lost if other requirements from one of the other 39 areas of the framework are prioritised. However, it can finally be said that the CFSR framework is by far the most elaborate in this analysis and accordingly offers the most information for an eHealth development if carried out adequately.

1.6. Exploratory research assumptions

The frameworks mentioned above showed different approaches to include stakeholders in the design and implementation process of an eHealth technology development. Each framework provides its guidance on how an eMental Health intervention should be developed. Nevertheless, each framework tries to involve stakeholders in the development process in its own way and simultaneously aims at avoiding all pitfalls. Based on the different approaches of the frameworks, the question is which framework most effectively involves stakeholders in the development process of an eMental health intervention. Also, to understand the usefulness of

stakeholders for the design and implementation process of an eMental health technology and for the overall development process of an intervention, the following research question is formulated:

” To what extent was the inclusion of stakeholders in the design and implementation process of specific eMental health technologies important for the development process?”

To answer the research question, the following sub-questions are formulated. Within the first sub-question, a comparison between different eMental health technologies and their approaches to including stakeholders is intended. Thereby strong and weak points of the inclusion of stakeholders can be identified.

Exploratory sub-question 1: “Which different approaches of stakeholder inclusion are used in the development of specific eMental health interventions?”

Furthermore, the importance of the information gained through the stakeholders is investigated. Therefore, the second sub-question is formulated as follows.

Exploratory sub-question 2: “Which insights did the company gain through the stakeholder inclusion, and to what extent did they contribute value to the eMental health technology?”

Finally, the approach of the companies for the implementation of stakeholders in their eMental health technology is evaluated. For this purpose, the structure and planning of the stakeholder inclusion are specifically addressed, and the experiences made with a possible framework are examined.

Exploratory sub-question 3: “To what extent was stakeholder inclusion for specific eMental Health technologies planned based on an implementation theory or framework, and which experience was gained with this structure?”

2. Methods

The goal of this study is to explore stakeholder inclusion during the development and implementation process of specific eMental health interventions. A qualitative, semi-structured interview method was chosen to gain a qualitative content analysis. Therefore, data for the research question as well as for the exploratory sub-questions was collected, following the instructions of Kuckartz (2014). Semi-structured interviews were chosen since they enable data gathering by offering a flexible way to extract information from experts. Thereby a framework for gaining insight into expert perspectives, thoughts, and expertise can be extracted (Kallio et al., 2016; Meyer & Booker, 2002; Hove & Anda, 2005). Also, through an interview guide, all

interviews contain the same structure, which enables comparison between the interview partners and to identify advantages and disadvantages within the process of intervention development and implementation.

2.1. Participants

The interview study was conducted on five eMental health companies originating from two different European countries, the Netherlands and Belgium (see Table 1). Before the interview study was conducted, two pilot studies with companies from the Netherlands and Italy were conducted (See Table 1). Therefore, the chosen language of the interviews was English. All identified companies brought an eMental health intervention to the market. The interview partners of the companies were identified based on specific inclusion criteria and contacted via email. The contact person of the interviewed companies should have been involved in the implementation and development of the technology or at least been informed about the most essential processes. Also, the eMental health technology should specifically support the mental health of informal caregivers who take care of their loved ones. Accordingly, only interventions that address, among other things or exclusively, informal caregivers were considered. Finally, an inclusion criterion was that the intervention provides interactive feedback and does not solely serve to obtain information.

Table 1

Interview partner interview study & pilot study

Name of the company of the interview study	Website	Description of the intervention	Job description of the interviewee	Country
Partner in Balance	https://www.partnerinbalans.nl/	Providing digital modules tailored to informal caregivers of dementia patients	Postdoctoral Researcher	Belgium
University Medical Centre Groningen	https://www.mantelzorg.nl	Mantelzorg Balans - Providing digital information and exercises tailed for informal caregivers.	Project Manager	Netherlands

Minddistrict	https://www.minddistrict.com/	Providing digital self-help modules to informal caregivers to support them in their daily life.	Implementation and integration Manager	Netherlands
Transfore	https://www.transfore.nl/ondersteuning-voor-naasten	Providing mental healthcare to informal caregivers of forensically treated patients.	Strategic policy advisor	Netherlands
Nedap	https://nedap-healthcare.com/oplossingen/luna/	Luna- a digital calendar application that helps informal caregivers to structure the daily life of their loved ones.	Product manager	Netherlands
Name of the company of the pilot study				
A Casa Ma non da Soli	https://portaledellacura.it/webinar/webinar-a-casa-ma-non-da-soli-1	A program for training targeted to families who have a member with some chronic condition. The program was conducted via the internet during the pandemic.	Assistant professor of sociology and economics	Italy
Minddistrict	https://www.minddistrict.com/	Providing digital self-help modules to informal caregivers to support them in their daily life.	Account manager	Netherlands

2.2. Materials

This thesis was conducted in the context of a PhD study on implementation of eMental health for caregivers. Therefore, an interview guide was created to ensure a consistent structure during the interviews. The basis for the guide was the above-mentioned implementation frameworks (CFIR, NASSS & CehRes roadmap). The interview guide (Appendix1) contained 12 open-ended questions that asked about three different subject areas. Thereby four different domains of implementation, which are commonly addressed in the employed frameworks, and their interplay are investigated further, namely: (1) the characteristics of the technology, (2) the

characteristics of the organisation, (3) the wider contextual elements (such as healthcare systems), and (4) the characteristics of the end users. The present work will focus on stakeholder involvement, but it profits from the other aspects of the interview guide as these questions explore a context for the stakeholder involvement. Concerning the technologies, the interview guide inquires the kind of technology that is used for the intervention and the way it works. Therefore, the first three questions related to the general orientation of the company, how the intervention worked, how the intervention was developed and what was particularly important. Subsequently, the focus was put on the organisation and the wider settings to request specific implementation knowledge as well as relationships between the company itself and external organisations or companies. For this porous, five questions about the implementation procedure were added to the interview guide. The wider settings enabled an understanding of the company's socio-political procedure as well as its economic structure and its coordination within the health care system. Finally, to gain knowledge about the adopters, four questions were asked about the stakeholders that are integrated into the design and development process. Here especially, the target group was inquired. Examples of open questions from the interview guide were "Who are your stakeholders?" and "What added value did you get from the stakeholders?". To test the interview guide and to give the researcher the possibility to practice the procedure, two pilot interviews were conducted.

Furthermore, an informed consent form (Appendix 2) was sent to the companies after they agreed to participate in the interview. It informed the participants about the intention of the study, explained that the interview could be withdrawn at any time and asked for permission to record the interview and to use the data obtained for scientific purposes.

The interviews were conducted through the video platform Microsoft Teams. Therefore, a webcam, a microphone and an existing internet connection were required. The interviews were recorded and transcribed via Microsoft teams. The coding software ATLAS.ti Mac (Version 22.1) was used to code the interviews. Also, an ethical approval (Appendix 3) has been submitted and approved by the University of Twente.

2.3. Procedure

In the beginning, potential interview partners were identified by the inclusion criteria mentioned above. Via email, an appointment for a video call was made. At the beginning of the meeting, the interviewer explained their intentions, and the interviewee was asked to send back the signed informed consent form. Then an audio recording was started, and the researcher started to ask the open questions from the interview guide. Answers that were too superficial

or not precise enough were investigated further by the researcher. After all twelve points of the interview guide had been queried, the researcher thanked the interview partner for their participation and ended the recording. The average interview took around 60 minutes, depending on the length of the answers that the interviewee gave. Due to a bad internet connection and insufficient knowledge of English of some interviewees, there were minor communication difficulties. However, with the repetition of questions and with the help of the automatically generated transcript, all questions were answered properly. After the transcript has been created and revised again by the researcher, the finished text document was sent back to the interviewees so that the company can check their statements again and release them for the research. In any case, the name of the interview partner was anonymised here.

2.4. Data analysis

In order to answer the given research question and thus examine the stakeholder inclusion in selected eMental health interventions, three sub-questions were created. First, "Which different and similar approaches of stakeholder inclusion are used in the development of specific eMental health interventions?", secondly "Which insights did the company gain through the stakeholder inclusion and to what extent did they contribute value to the eMental health technology?" and finally "To what extent was stakeholder inclusion for specific eMental Health technologies planned based on an implementation theory or framework and which experience was gained with this structure?". The coding scheme was created based on these three sub-questions. All interviews were first analysed inductively by defining three codes that were assigned to the three sub-questions. Afterwards, a deductive analysis was carried out by dividing the quotes of the three codes into further sub-codes. To ensure reliable results, a double coding method is used to verify the coded quotes from the interviews. Therefore, the quotes were counter-read and checked by another researcher and a supervisor controlled the final coding scheme.

3. Results

3.1. The coding scheme

A total of 18 codes were identified from 5 interviews and 2 pilot interviews (See Table 2). With regard to the first research question, "Approach of stakeholder inclusion" was first coded and then divided into the subcategories "Collaboration", "Interview", "Questionnaire" and "Usability study". The "Collaboration" category was also subdivided into "Collaboration with a company" and "Collaboration with an expert".

Concerning the second research question, the code "Value gained through stakeholder inclusion" was first defined. This code was then divided into the three subcategories "Core value of the intervention", "Insights for the intervention development", and "Value for improvement in the future".

The third question was tackled in two parts. First, the interviews were coded to "Experiences with the framework/theory" and "Theoretical background of stakeholder inclusion". Then the code "Experiences with the framework/theory" was divided into "Positive experiences" and "Negative experiences". The code " Theoretical background of stakeholder inclusion" was then divided into "Economic background", "Name of the framework", and "Theoretical procedure". The prevalence rates of all codes, together with the definition of each code, can be found in table 2.

Table 2

Prevalence of codes from the interviews

Name of the Code	Name of the Subcode	Definition of the Code	Frequency
Question 1: Approach of Stakeholder Inclusion		Quotes that indicate stakeholder involvement in the development and implementation process	100
	Collaboration (total)	Quotes that indicated a collaboration with stakeholders	61
	Collaboration with a company	Quotes that indicated collaborations with other companies	36
	Collaboration with an expert	Quotes that indicated a collaboration with an expert	28
	Interview	Quotes that indicate stakeholder inclusion through interviews	24

	Questionnaire	Quotes that indicate stakeholder inclusion through questionnaires	6
	Usability study	Quotes that indicate stakeholder inclusion through a usability study	7
Question 2: Value gained through stakeholder inclusion		Quotes that indicate value gained through stakeholders	75
	Core values of the intervention	Quotes that implicate core values gained through stakeholders for the intervention	19
	Insights for the intervention development	Quotes that implicate insights for the development of the intervention gained through stakeholders	40
	Value for improvement in the future	Quotes that implicate insights for improvement of the intervention in the future gained through stakeholders	18
Question 3 (1/2): Experiences with the theory/ framework		Quotes that indicate experiences that were collected with a specific implementation theory of framework	85

	Positive experiences	Quotes that indicate positive experiences with a theory/ framework	18
	Negative experiences	Quotes that indicate negative experiences with a theory/ framework	63
Question 3(2/2): Theoretical background of stakeholder inclusion		Quotes that indicate a theoretical strategy that was used for the involvement of stakeholders in the product development	66
	Economic background	Quotes that indicate insights into the financial aspects of the company	16
	Name of the framework	Quotes that indicate specific names of theories and frameworks that were used for the product development and implementation	12
	Theoretical procedure	Quotes that indicate a specific procedure within development and implementation	43

3.2. Outcome of the coding scheme

3.2.1. Approaches of Stakeholder inclusion

With reference to the first sub-question, "Which different approaches of stakeholder inclusion are used in the development of specific eMental health interventions?", first, the code "Approach of stakeholder inclusion" was defined. An example of this code is the following quote: "*In terms of implementation, what was very interesting was working with our technology company or technology partner".* This code was chosen to explore the different approaches used by the companies to involve stakeholders in their intervention development process. Generally, all of the interview partners from all countries who were interviewed dealt with stakeholders in relation to the development of the intervention. Each intervention surveyed has adapted specific development processes to engage with external stakeholders. The list of identified stakeholders includes external business partners, like, external experts, or external companies that were involved in the development process of the intervention. In addition, the target group was identified as a stakeholder by almost all of the companies that were surveyed. Other identified stakeholders were healthcare workers. On the one hand, employees of health insurance companies clarify the financial details in relation to covering the costs and adapting the intervention to the standards of the healthcare company. On the other hand, nurses or psychotherapists which use the intervention themselves and bring it to the customer. However, there were a wide variety of methods and approaches for identifying stakeholders and obtaining their requirements for the intervention.

3.2.1.1. Interview

The first method for engaging with stakeholders is through interviews. Five out of seven companies included in the survey used interviews. On the one hand, to develop the intervention and, on the other hand, to evaluate and improve the already implemented intervention. An example is the following quote: *"we interviewed 14 stakeholders"*. The questioned companies used interviews specifically to collect data from informal and formal caregivers and the patients themselves. One company developed its own interview guide for this purpose, while other companies used existing interviews or gave no information on the type of interview. However, only three out of these five companies used interviews for the development and implementation phase, whereas two companies only used them as an evaluation method. Also, the use of interviews was mainly found in reference to external professionals but not to the actual target group. Therefore, the companies did not fully use the potential of interviews as an information gathering method.

3.2.1.2. Questionnaire

Another approach for gaining information from stakeholders within the "approach of stakeholder inclusion" code was questionnaires. An example of the code "questionnaires" is the quote: *"we decided to do two shared dissemination questionnaires, one for informal caregivers and one for care professionals"*. Only 4 out of 7 target companies used questionnaires for stakeholder inclusion. Like the "Interview" code, it became apparent here that questionnaires were only used to gain information from informal caregivers but not from other stakeholders. Here, too, it is noticeable that the method was largely used for evaluation but not for product development.

3.2.1.3. Usability Study

The final method relevant to stakeholder inclusion for the first sub-question is usability study. An example of this is: "*in the development of the tool, we continuously asked informal caregivers to review our versions and comment on that"*. Unexpectedly, this method for the stakeholder's inclusion was only used by two of the questioned companies. It should be mentioned here that five companies did not check whether the developed intervention was tailored to the target group.

3.2.1.4. Collaboration (total)

A different approach to stakeholder integration is a collaboration. One quote is: *" for developing the tool, we work together with the software company"*. Collaboration in this case is not a specific method for stakeholder inclusion. In general, the approach of including stakeholders through collaboration can be engaged through both companies as well as individuals. All seven interviewees entered into a collaboration with external stakeholders in connection with their product development. A collaboration was entered into when the company surveyed revealed knowledge gaps in the course of their intervention development. For example, many of the companies surveyed were not sufficiently familiar with programming a website, which is why this task was often outsourced. The type of collaboration depends on the size of the company. Big companies that have been interviewed had on the one hand, cooperation with extern companies that take over the economic part of the intervention or, on the other hand, employed employees who took on these tasks. However, the smaller the company is, the more likely it is to outsource such economic tasks to external individuals.

3.2.1.4.1. Collaboration with a company

A collaboration with an external company was coded in the interviews a total of 30 times. An example for this code is: *"in terms of like the background and like updating (...) and*

you know that's a bit more complicated, but it's also not my job, it's not our job, it's the technical companies' job". What can be clearly seen here is the cooperation with a technology company that is responsible for the technical implementation of the eMental health intervention. Since all companies had little previous knowledge in this area, this seems to be a common way to implement technical aspects efficiently into an intervention development. Furthermore, almost all companies have worked with government organisations and health insurance companies to best adapt their interventions to the market. The interviewees considered these kinds of cooperations as valuable for the intervention since they provide insights into the problem that is aimed to be solved. However, the inclusion of the stakeholders from the mental health sector also adds the advantage to the companies that when these institutions are incorporated in the intervention, they are more likely to integrate the intervention into their working environment. Thereby they not only serve as information providers but also as representatives of the intervention. On an international level, it can be said that all the companies surveyed collaborate similarly with technical companies, government organisations and health insurance companies.

3.2.1.4.2. Collaboration with an expert

A further collaboration took place among all interview partners with an expert. An example of this is the following quote: *"we have a health economist that comes in sometimes based on the project we're working on, or we also have two clinicians, two psychologists that work with us"*. Some companies realised, that they needed support with specific fields of expertise. These experts are specifically selected to fill knowledge gaps in the companies. Therefore, the areas of expertise differed for all interview partners. Nevertheless, concerning eMental Health interventions, especially cooperation with psychologists, psychiatrists, neurologists, and nurses, can be recognised. However, also on an economic level, cooperation with case managers, project managers and integration and implementation managers could be identified at individual companies. Generally, the approach of including stakeholder trough a collaboration is a similarity that was discovered in all intervention development processes of all interview partners.

3.2.2. Insights and values through stakeholder inclusion

The second exploratory sub-question, "Which insights did the company gain through the stakeholder inclusion and to what extent did they contribute value to the eMental health technology?" was investigated with the code "Value gained through stakeholder inclusion". An example of "value gained through stakeholder inclusion" is: "*of course the product itself*

has to be easy and easy to use because not all therapists are waiting for using an online product. So, you have to make it as easy as possible ". All interview partners have learned values and requirements from stakeholders. Nevertheless, these values differ in their possible applications. For the most part, the values are guidelines for proceeding with and developing the desired intervention. Nevertheless, essential values for the functioning of the intervention were also identified. Through different evaluation processes, values were also discovered that could be useful for future interventions.

3.2.2.1. Core value of the intervention

All interviewed companies have integrated the core values of stakeholders for the development of their intervention. An example is: "*the leading principle was with self-management"*. The core values that were discovered differ depending on the target group and the intervention itself. The guiding principles of all eMental health interventions are self-management, self-efficacy and ease to use. All core values contributed a great deal to the development of the intervention. With regard to the stakeholders in connection with the target group, however, a differentiation must be made. Informal caregivers expressed not all integrated values. Since many interviewed companies cooperate with other companies and, among other things, sell their product through external companies, many values from external companies were also integrated into the intervention, such as findability well marketed or preventive care. Nevertheless, many values were also identified at the request of informal caregivers and integrated into the intervention, such as ease of use, accessibility, trustworthiness, and effectiveness.

3.2.2.2. Insights for intervention development

Other values that were filtered out of the interviews were used by the companies to develop the intervention. An example is: *" We always sort of saw the target group of (us) as being the caregivers of people with dementia because yet that's the target group. But in the end, we're looking at the implementation. You have two target groups. You have the caregivers, and you have the coaches because if the coaches aren't comfortable using the tool, then it won't get used, and you won't reach your target group"*. This code entails almost exclusively information obtained through cooperation with external companies or experts who gave the interviewed company tips and recommendations for the development of the intervention. These are topics of digitalisation and how the intervention has to be designed so that it works smoothly on all devices. Alternatively, also about the economic development of the company so that it can finance itself sustainably. Most of the companies that were interviewed were still very

young and therefore still so small that not all employees had all the necessary expertise. That is why extern help is a good option since professional freelancers already have the experience that companies can benefit from. Accordingly, it can be said that external help has potentially great value in optimising the intervention.

3.2.2.3. Value for improvement in the future

The last sub-code for the second exploratory research question is "Value for improvement in the future". An example of the "Value for improvement in the future" code is provided by the following quote: *"we have a problem of the lack of health care facilities in our mountain areas. And so, we think it's the future, but we need a really careful planning to overcome all the difficulties we have yet"*. These codes consist mainly of citations of lessons learned from evaluation strategies and bugs discovered early in the development phase. Only 4 out of the 7 surveyed companies mentioned future improvement suggestions. As already becomes evident in the different implementation strategies from the introduction, an evaluation strategy is essential for sustainable product implementation. As already mentioned in the results of the first sub-question, the companies interviewed mainly used questionnaires and interviews as evaluation methods. The theoretical orientation towards the CeHRes roadmap framework also entails an evaluation instance. Values gained through evaluation were nonetheless increased stakeholder inclusion and greater reference to a theory or framework related to intervention development in the future. It can therefore be concluded that the companies involved in e-mental health interventions have not yet placed a great deal of focus on evaluation. It must be said that the companies surveyed are very young companies that have only recently brought their product to market. Nevertheless, a lack of stakeholder inclusion can be observed in the intervention development and evaluation process. A reliable evaluation method was criticised within the companies, and it was subsequently determined that more stakeholder inclusion in the development and implementation process would have been helpful. It can also be added that interviews and questionnaires were mainly applied to the target group and thus to informal caregivers, but not to other stakeholders such as external companies or experts or cooperating professionals from the healthcare sector.

3.2.3. Use of theory and framework

From the third exploratory sub-question, "To what extent was stakeholder inclusion for specific eMental Health technologies planned based on an implementation theory or framework and which experience was gained with this structure?" two underlying elements were

identified. Namely “Experiences with the framework/ theory” and “Theoretical background of stakeholder inclusion”.

3.2.3.1. Experiences with the framework/theory

On the one hand, the "Experiences with the framework/theory" code was created. An example of this code is: *" (we) used to have a forum, but it wasn't used. It was quite scary for people to use um, so we got rid of that after the process evaluation".* All companies that were interviewed shared their experiences with the theories and frameworks used, which were divided into positive and negative experiences within this code.

3.2.3.1.1. Positive experiences

The positive experiences code was applied to 6 out of 7 interviews. An example is: *"So, we try to do the usability testing’s also online to speak to people which sharing screens and letting them walk through the tool and well thinking aloud. So that's quite easy to do online. Also, it saves a lot of travelling time. So that was really helpful*". The interviewees who provided information gained predominantly positive experiences with the customer and collaboration company contact that is prescribed by theories. Furthermore, a positive experience was gained with specific theories that supported the implementation and thus ensured a smooth market launch. This was achieved mainly by providing lists of steps to consider for product implementation, thereby ensuring that no step was forgotten. However, one point of criticism must be mentioned in this context. The theories refer to an ideal starting position that cannot be found in real life, and the implementation of the given instructions is accordingly much more complex than mentioned in the given theories and frameworks. Nevertheless, stakeholder inclusion was recommended in the theories and frameworks mentioned, which is why the companies that used a theory or framework included stakeholders in the development and implementation process.

3.2.3.1.2. Negative experiences

Negative experiences in relation to the theory used or the framework were mentioned much more often than the "positive experiences" code. All of the interview partners provided information on this topic. An example is: *"So I wouldn't say it's quite where I want it to be in terms of implementation because that would be that it was self-sustaining and no longer dependent on research grants".* Negative experiences were also mentioned in connection with the theories and frameworks. As can be seen from the results, the criticism is not about missing steps or instructions but rather about the details. Although the theories and frameworks guide stakeholder inclusion, the companies interviewed had the experience of not involving enough

stakeholders in the development process. The same problem can be related to the economic specifications of the theories and frameworks. Although theories such as CeHRe's roadmap contain a very detailed business plan, this does not apply to all theories. Accordingly, despite specific requirements, companies have had negative experiences with the economic aspects of their intervention. In addition, some interview partners had problems convincing stakeholders from the health sector of their intervention, as they were afraid of losing their jobs or their raison d'être through the technology. At this point, it must be said that no theory addresses this problem precisely. While some theories also address ethical issues, no solution is offered as to how such a problem can be solved.

In conclusion, it can be said that the experiences with the theories are divided into two. On the one hand, the theories provide structure and guidance on how an intervention can succeed. On the other hand, the given structure is not detailed enough and not tailored to each intervention. Despite using such a theory, crucial mistakes were still made that could have been avoided.

3.2.3.2. Theoretical background of stakeholder inclusion

On the other hand, the code "Theoretical background of stakeholder inclusion" was defined, which summarises the theoretical approaches of the interview partners. An example of this is: *" We had a small report and based on that, and we decided to design flyers. So, there's something physical to hand over or to place in waiting rooms and short videos. So, instruction videos because people didn't need anything more about this website and I think that's correct because it's quite easy to use website".* All citations that provide insight into the theory behind the development of the intervention are summarised under this code. Each interviewee provided information about the theoretical background of the product and their own company.

3.2.3.2.1. Economic background

The code "Economic background" contains all statements about the theoretical approaches of the financing of the organisation and the sale of the intervention. An example of this code is: *"once we really got into like the financing side of things, we've used the business model Canvas a lot".* Five of the seven surveyed companies provided information on the financial theory behind the intervention. Many interviewees mentioned in this context that different types of organisations support them. On the one hand, this is support from the government or health insurance companies. On the other hand, interventions grew out of academic work, leading to funding from universities. Furthermore, some companies reported

that they created a business model themselves to plan the financing of their intervention. The theories mentioned in this context were the diffusion of innovation theory and the business model canvas from the CeHRes roadmap. These theories make demands on the company that must be met in order to achieve financial success as a company. Thereby it can be concluded from the company's point of view which tasks can be completed internally and for which tasks external help is required. Concerning financial planning, it can be said that five out of seven companies provided information about the financial orientation of the company and were able to derive important stakeholder inclusion from this.

3.2.3.2.2. Name of the framework

Furthermore, the different names of the frameworks were collected under the code "Name of the framework". An example of this code is: " *the project was based on the CeHRes roadmap of the University of Twente* ". Only 4 out of the 7 companies that were surveyed named a specific theory or framework that was used to develop and implement the intervention. These included the medical research council framework for complex interventions, the acceptance and commitment theory, the CeHRes roadmap, the intervention mapping technique, and the diffusion of innovation theory. The medical research council framework for complex interventions was developed by the medical research council and intended to support researchers in recognising appropriate methods for their research (Craig et al., 2008). The focus of the framework is put on evaluation requirements that need to be considered during the planning phase of an eHealth intervention. Thereby, the effectiveness of the intervention can be tested before the intervention is put on the market, whereby a successful implementation is established (Craig et al., 2008).

The mindfulness acceptance commitment theory states that goal-oriented behaviour can be achieved by accepting one's memories and, at the same time, behaving appropriately to the situation (Gardner & Moore, 2007). As a result, competitive behaviour, problem-solving skills and decision making can be enhanced through acceptance and commitment (Gardner & Moore, 2007).

The intervention mapping technique is a framework for eHealth intervention development (Bartholomew et al., 1998). It is based on the three main activities for problem-solving in health education. Namely, needs assessment, program development and evaluation. Based on five steps, the intervention mapping technique guides the development of eHealth interventions. These are (1) creating a matrix of objectives (2) selecting appropriate methods and strategies based on the objectives (3) organising and designing a program (4) specifying

implementation and adoption plans, and (5) creating an evaluation method (Bartholomew et al., 1998).

The diffusion of innovation theory offers guidance for adopting a new idea, a new product or even a new philosophy by society (Kaminski, 2011). The target group is divided into five groups and sorted according to the order in which they adopt something new. According to the theory, the so-called innovators must first be addressed. These spread the new "product". If there is some acceptance of the product, society will automatically take notice. The first to start using the product are called early innovators. They are followed by the early majority, which are then followed by the late majority. Finally, the laggards and the non-adopters follow. Based on this division, the theory offers guidance for how each subgroup of society can be differently convinced of the product to optimise an implementation process (Kaminski, 2011).

One company that was interviewed also explained that they invented their method for developing and implementing their intervention. Another company indicated in this regard that they do not use a direct method to develop and implement the intervention. Accordingly, it can be concluded that, on the one hand, five out of the seven companies that were surveyed have dealt with a theory or framework in advance, which also provides for stakeholder inclusion. Two out of seven companies, on the other hand, brought their product onto the market without theoretical help but had various difficulties and setbacks, resulting in an adaption of the product after the publication.

3.2.3.2.2. Theoretical background information

Finally, the "Theoretical background information" code is considered. It is not directly related to any theory or framework that recommends stakeholder inclusion. However, the code documents work steps within the intervention development and implementation, which are based on statements from external companies and experts. Accordingly, stakeholder inclusion can be traced back to this. An example of this code is: "*That's when we really took the first steps in thinking about a business model, piloting it in a bunch of different contexts, like the municipality. Certain health care organisations that a lot of interviews talking about what could be paid for this? Is it OK to pay for it? Who would pay for it? "*. All of the questioned companies provided information about their approach during product development and preparation for implementation. On the one hand, the cooperation with external companies is explained in particular, for example who carried out which task and how the product was developed and tested. On the other hand, the companies reported on their evaluation methods.

In this context, the use of interviews and questionnaires is mentioned, which should help to further improve the intervention according to the wishes of the target groups. An exception was made by one company that was surveyed, as they did not test their intervention but launched it directly on the market.

4. Discussion

4.1. Main Findings

Based on the results, the following conclusions can be drawn from the interview study for developing an eMental Health intervention. Working with external parties to fill knowledge gaps is a valuable approach to involving essential stakeholders in the development process of an intervention. The interviewed companies used external companies and experts when it came to developing business models or technical applications like a website. This finding is consistent with earlier studies such as that of Laband and Tollison (2000). Laband and Tollison (2000) compared an expert with a group of less experienced researchers. As a result, it was concluded that the expert's knowledge was less detailed than the knowledge attained through the combination of the knowledge of the group of less experienced researchers. The combination of the knowledge of a group was called a knowledge network. It was concluded that the knowledge network has more success in the expertise sector than the expert alone (Laband & Tollison, 2000). The same can be said about the collaborations in the eMental health field. It depends on the company's size whether a company should collaborate with an expert or an external company. Nevertheless, covering knowledge gaps with external experts can have a constructive influence on developing an eMental health intervention since it improves the creation of a knowledge network for the intervention and provides more detailed information for the intervention development. It can be concluded that the quantity of stakeholders should be considered as much as the quality of the stakeholders.

Another insight gained from the results of the interviews is that the methods "interviews" and "questionnaires" could potentially be used more effectively. Both methods were used by the interviewed companies several times. However, the missed potential is caused by the application of the two methods. This is the case as, on the one hand, both methods are only applied to gain information from the target group of the intervention but not from any other relevant stakeholders. On the other hand, the methods were used mainly for evaluation purposes to measure the satisfaction of the target group. Here, the methods were used exclusively to gather information from the target group, but other relevant stakeholders were not considered. On top, the application of interviews and questionnaires was neglected during

the development phase of the intervention and mostly used as an evaluation instance. However, the importance of these two methods for an eHealth intervention development is stressed by Gemert- Pijnen and colleagues (2018), as it contributes prominent insights into the contextual need of the stakeholders. Therefore, it can be concluded that a correct application of the two methods of questionnaire and interviews could have contributed to gathering more insights during both the development and evaluation phases. As a conclusion, the lack of application of the two methods to all other stakeholders except the target group, explains the missed potential.

A very unexpected result was the limited use of usability studies. Only two of the seven interviewed companies did a usability study before launching their intervention. Accordingly, five companies did not test their product on the target group and therefore could not provide information about their intervention's effectiveness. Therefore, the full potential of the "usability study" method was not used here either since early adjustments during the development phase of the eMental health interventions were neglected. This result is in line with the literature that underlines a usability study's importance and value (Bastien, 2010). Only with the application of a usability study errors can be identified, and adjustments can be made in an early stage (Bastien, 2010). Thereby a usability study enables that the intervention can be tailored to the target group and that the intervention is not misused when launched to the market. Thus, the interventions of the interviewed companies could have had more market launch potential if they had made use of this method. It should also be mentioned that the CeHres roadmap, for example, guides conducting a usability study in the development process (Gemert-Pijnen et al., 2018).

Another important insight was gathered with regard to the theories and frameworks used by the interviewed companies. For the code "values gained for the future," the companies elaborated that every theory and framework used during the development process guided stakeholder inclusion. In conclusion, the inclusion of stakeholders into the development process an eMental Health intervention took place. Nevertheless, including even more stakeholders was seen as valuable for future eMental health development. However, the procedure was insufficient to optimally adapt the intervention to the target group, which is why more stakeholder inclusion would have brought increasing clarity about the requirements and needs of the stakeholders involved in the intervention. As a result, the effectiveness of the intervention has decreased since weak points that could have been avoided were taken over. This finding is in line with the literature, for example, a meta-analysis of the intervention development for the treatment of HIV (Henny et al., 2018). Here, it was found that

interventions that followed the guidelines of a theory exploit significantly more potential in optimising the intervention than interventions that do not follow the guidelines of a theory or framework (Henny et al., 2018). The non-adherence of the intervention developers concerning the use of a theory, or a framework can therefore criticised.

Another main finding is the limited use of evaluation methods by the companies surveyed. During the development phase, the interviewees did not consider any evaluation methods. Only after the intervention was launched to market the companies stared testing the intervention for its effectiveness. Although an evaluation is recommended in many theories and frameworks, the companies hardly planned any procedure in this regard. It was stressed by Catwell and Sheikh (2009) that continuous evaluation of technology is essential for the longevity of the intervention. Only through constant adaptation during the design phase and after the launch can the maximum potential and maximum benefits be achieved from the intervention (Catwell &Sheikh, 2009). It can therefore also be concluded that the companies did not use the full potential of the evaluation methods. As a result, the interventions could not reach their full potential.

Furthermore, the orienting toward a theory or a framework has generally turned out to be helpful for the companies surveyed. It could be determined that significantly fewer complications occurred during development and implementation if guidance from literature was followed. Especially the guidance of economic aspects of the eMental health interventions turned out to support the companies. Through this guidance, the companies became aware of the financial requirements that intervention needs to fulfil to be launched sustainably on the market. Furthermore, from these requirements, the companies could assess which requirements can be fulfilled by the company itself and which tasks need to be outsourced to external parties. As a result, more reliable business models could be developed, and the interventions had more potential to assert themselves in the market than interventions that did not use a theory or framework as guidance (Gemert-Pijnen et al., 2018).

Finally, the interviews revealed that involving stakeholders in the development process of an eMental health intervention is of great benefit. In particular, the derivation of core values from the target group ensures a tailor-made intervention. This is also confirmed by the literature, which regards the target group as a key stakeholder in the contextual inquiry (Gemert-Pijnen et al., 2018). Moreover, the companies benefitted from other advantages as a result of involving stakeholders. Companies benefit from cooperation with health insurance companies. This ensures that the intervention is adapted to the standards of the health insurance

companies. The exact process can also be achieved by involving workers from the healthcare sector. If, for example, a psychiatrist or a nurse is involved in the development of the intervention, it can be ensured that their wishes and requirements are incorporated into the intervention. In conclusion, this means that the collaboration partners are more convinced of the intervention, as it fulfils their requirements and communicates this to the target group (Gemert-Pijnen et al., 2018).

4.2. Comparison, limitations & strengths

Despite the orientation through literature, adverse experiences were made in stakeholder inclusion and evaluation strategies within this study. Compared to similar studies, certain similarities can be identified. For example, an interview study examining the so-called FITT framework for intervention development in eHealth found that stakeholder inclusion was often neglected (Kujala et al., 2020). It should be mentioned that the FITT framework guides stakeholder inclusion. Nevertheless, it was found that the interviewed intervention developers did not use the guidance of stakeholder inclusion as intended by the framework. Therefore, Kujala and colleagues (2020) suggested a point of improvement to include more detailed stakeholder inclusion guidance into the framework (Kujala et al., 2020). Based on these two experiences, criticism of the frameworks can be expressed since they apparently cannot imply the importance of stakeholder inclusion in the intervention's development. Nevertheless, the literature confirms that involving stakeholders in the development and implementation process greatly benefits aligning the technology with the target group.

The work of Neher & Colleges (2020) offers another perspective on stakeholder inclusion. Regarding stakeholders from the healthcare sector, it was found that the demands of stakeholders from the health sector on eHealth interventions and their barriers vary greatly (Neher et al., 2020). This is the case since the health care stakeholders do not have a uniform idea of requirements, challenges, and policies for a specific eMental health intervention (Neher et al., 2020). Therefore, the inclusion of different stakeholders from the health sector does not provide equal insights for the intervention developers. In conclusion, the more stakeholders, especially from the health care sector, are included in the development process, the more likely it is to receive a general claim to the intervention. Again, reference can be made to the knowledge network mentioned above. The more people work on the development, the better the intervention can support its target groups. This finding is consistent with the experiences of the companies surveyed since, although they involved stakeholders in the development

process, they only learned afterwards that more stakeholders would have improved the intervention development process.

One strength was identified in the frame of this study. The biggest advantage that provided a lot of context information for the study was the interview guide. The guide was developed for a PhD study and requested much information that was not specifically useful for the research question but gave a lot of helpful contextual information in order to understand and interpret the information that was discussed. A clear understanding of the companies' intervention development could be deducted from the requested background information.

However, several limitations were identified as well. First, only two pilot studies and five complete interview studies were conducted. Accordingly, the informative value of the data obtained is marginal. In order to be able to make more precise statements about the development of eMental Health interventions, more data must be collected in the future. In addition, there were minor complications during the interview study due to the internet connection, which hampered the flow of the dialogue, which would not have occurred during a face-to-face interview. Furthermore, a particular language barrier can be identified in the interviews since the interviews were conducted in English and not in the mother tongue of the interview partners. Therefore, more reliable data can be collected in the future if the interviews between researcher and interviewee are based on a common mother tongue and, in the best case, take place face to face. Another limitation of interest for future research is the inclusion of a variable called "success of the intervention". Of course, it must be said that all the companies surveyed are, to a certain extent, successful with their intervention since all interventions were brought to market and are also holding their ground there. However, this study did not directly inquire about the success of the intervention and included it in the evaluation. In the future, more accurate comparisons between different companies could be made by considering this variable since it can provide weight for a specific procedure of a specific company.

4.3. Conclusion

Within the framework of this study, the importance of stakeholders for the development process of eMental health interventions was explored. In conclusion, it can be said that stakeholders have a great influence on the potential of an intervention. They shape it with their own requirements and values so that the finished intervention is tailored to the target group. Nonetheless, this study made it clear that the theories and frameworks developed for the development of an eHealth intervention should have an even stronger focus on stakeholder

inclusion. However, it should be mentioned that this qualitative study does not allow any significant statement to be made about an entire eHealth industry, but only about the companies surveyed. For this reason, future research should focus on a more significant number of participants so that a quantitative study can lead to significant results. In addition, other theories and frameworks can be examined to incorporate their motives into an interview guide and explore them. The more different theories and frameworks are examined, the more guiding motives for a successful intervention can be identified. Furthermore, key stakeholders can be further investigated so that, for example, questions such as "How many stakeholders are too many and which stakeholders are of highest importance for the success of eMental health interventions?" can be answered. In the long term, this can be used to deal with the topic of how stakeholder inclusion can be conveyed in the best possible way through a theory or framework so that a universally applicable theory or framework is ultimately created. A final direction in which this research could be taken further would be to explore how much influence the target group has on the development process of different eHealth interventions.

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Appendix 1: Interview guide

Interview guide for semi-structured interviews with Implementation Specialists at eHealth organisations delivering web-based interventions to improve mental well-beingwell-being of informal caregivers

Space for mutual introductions

Ok, let's start with a couple of general questions:

1) How would you describe your technology/service in a couple of sentences? (What is it, what does it do? What are the most important things to say about it?)
2) Tell me about the creative process? How did the idea come to life? (Specific need to address, ties with academia, tested for efficacy?)
3) What about the values it incarnates? (Value based design, value specification, value proposition)

Ok, thank you. Now, I would like to ask you some questions about implementation

4) What is your role in the organisation? Who else is involved in implementation (formally or informally)?
5) In which stage it is?
6) Did you follow an implementation plan?
7) Did you follow a framework or theory to guide implementation (how did you chose this one?)
8) Did Covid interfere with your implementation? (How?)

Great, now the idea is that I will present to you several general themes. I will ask you to reflect on how these themes influenced the implementation of the technology.

9) Attributes of the technology itself? Hardware? How do you deal with updates and technical support?
10) Organisational context? (Relationships with local organisations, specific implementation knowledge, etc)
11) Wider context? (Socio-political, economical, healthcare)
12) Stakeholder involvement? (Who are they, how they were identified, what is the specificity of dealing with caregivers, were they involved in design/distribution, other

phases, what was the added value, describe the process, what challenges did you encounter?)

As a last question, can you think of any other technologies that I might want to involve in my case study? Is there someone else you think I would benefit from talking to?

Thank you, the interview is finished. As part as a short follow up, I will fill in a Business Model Canvas regarding your intervention and share it with you, would you be willing to complete it?

Appendix 2: Informed consent

Informed consent form for research with human participants

Dear Participant

Thank you for your permission to be interviewed.

This research is being conducted by Sofia Bastoni from the University of Twente, as part of the ENTWINE ITN Consortium (https://entwine-itn.eu).

The purpose of this interview is to understand how eHealth innovations and technologies to support Informal Care are successfully implemented in practice. Think about how implementation was handled within your organisation, what was needed for the implementation of your innovation, what stage of implementation does your innovation find itself in, who are your key stakeholders, how the technology was conceived and how does your context operate. We are interested in your professional opinion and findings, therefore there are no right or wrong answers. In connection with the duration of this assignment, we also wanted to ask if you are available for a short follow up (via email). The interview will last approximately 45 minutes, but you have the right to stop the interview at any time and without giving any explanation.

For the sake of processing this interview, we would like to record the meeting. If you are not comfortable with video recordings, you can turn off your camera at any point. With those recording(s) we can transcribe and quote the interview. All names, places and dates will be made anonymous. The recordings are stored securely according to the UT data management system for transcription of the interview. After the transcriptions, the recording will be destroyed. Some of the information or experience you will share may be confidential and you might not want it to be used for research

purposes. If you do not wish for us to share certain information you can let us know so that we can handle it discreetly. The anonymised transcript will be shared with you once completed and you can also indicate that we cannot use certain information later.

This research project has been reviewed and approved by the BMS Ethics Committee. No specific risks are envisioned with the participation to this study. Ethical procedures for scientific research, conducted by the Ethics Committee of the Faculty of Behavioral, Management and Social Sciences (BMS) of the University of Twente require that the interviewees explicitly agree to the interview and how the information will be used in their interviews. This consent form is necessary for us to ensure that you understand the purpose of your involvement and that you agree to the terms of your participation.

Therefore, please read the attached consent form and then sign this form to confirm that you agree to the following.**Consent Form for "Successfully implemented technologies to support informal care: multiple case study"**

YOU WILL BE GIVEN A COPY OF THIS INFORMED CONSENT FORM

Please tick the appropriate boxes

Taking part in the study	**Yes**	**No**
I have read and understood the study information dated 17/02/2022, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	□	□
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time without having to provide a reason.	□	□
I understand that taking part in the study involves participating to a video recorded online interview for the duration of 45 minutes approximately and a short follow up in the form of email exchange. The recordings will be transcribed and deleted right after. I will receive the transcription and will have the possibility to retract any information that I am not comfortable with sharing.	□	□

Use of the information in the study

I understand that information I provide will be used for scientific publication purposes. The interview (s) will be analysed, and the result will be reported to describe the implementation of eHealth solutions to support informal care. Furthermore, the publication will be part of the researchers' doctoral dissertation. No other use is envisioned for the data.	□	□
I understand that personal information collected about me that can identify me, such as [e.g., my name or where I live], will not be shared beyond the study team.	□	□
I agree that my information can be quoted in research outputs.	□	□
I agree that my company name can be used for quotes.	□	□
	□	□

Future use and reuse of the information by others

I give the researchers permission to keep my contact information and to contact me for future research projects.	□	□

Signatures

Micol Bronzini		17/02/22
Name of the Interviewee	Signature	Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Sofia Bastoni		17/02/22
Name of the Researcher	Signature	Date

Study contact details for further information: Sofia Bastoni, University of Twente Drienerlolaan 5, 7522 NB, Enschede, The Netherlands. Email: s.bastoni@utwente.nl Phone: +31 53 489 5284)

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the Secretary of the Ethics Committee of the Faculty of Behavioural, Management and Social Sciences at the University of Twente by ethicscommittee-bms@utwente.nl

Appendix 3: Ethical approval

UNIVERSITY OF TWENTE.

FACULTY BMS

220018 REQUEST FOR ETHICAL REVIEW

Request nr: 220018

Researcher: Bastoni, S.

Supervisor: Gemert - Pijnen, J.E.W.C. van

Reviewer: Klooster, P.M. ten

Status: Approved by commission

Version: 2

1. START

A. TITLE AND CONTEXT OF THE RESEARCH PROJECT

1. What is the title of the research project? (max. 100 characters)

Successfully implemented technologies to support informal care: multiple case study

2. In which context will you conduct this research?

PhD project

3. Date of the application

18-01-2022

5. Is this research project closely connected to a research project previously assessed by the BMS Ethics Committee?

Yes

please provide the ethic request number(s) for the research project(s):

211229

B. CONTACT INFORMATION

6. Contact information for the lead researcher

6a. Initials:

S.

6b. Surname:

Bastoni

6c. Education/Department (if applicable):

BMS-PGT

6d. Staff or Student number:

76683507

6e. Email address:

s.bastoni@utwente.nl

6f. Telephone number (during the research project):

+31534895284

6g. If additional researchers (students and/or staff) will be involved in carrying out this research, please name them:

2 students: to be assigned

6h. Have you completed a PhD degree?

No

7. Contact information for the BMS Supervisor

7a. Initials:

J.E.W.C.

7b. Surname:

van Gemert - Pijnen

7c. Department:

BMS-PGT

7d. Email address:

j.vangemert-pijnen@utwente.nl

7e. Telephone number (during the research project):

+31534896050

8. Is one of the ethics committee reviewers involved in your research? Note: not everyone is a reviewer.

No

C. RESEARCH PROJECT DESCRIPTION

9a. Please provide a brief description (150 words max.) of the background and aim(s) of your research project in non-expert language.

This project aims to deepen cases of successfully implemented technologies to support informal caregivers. Informants were recruited in a prior stage to recommend examples of technologies they have come across. At this stage, contact people within the technology organizations identified during the previous stage will be interviewed. The qualitative data will be analyzed though thematic analysis.

9b. Approximate starting date/end date of data collection:

Starting date: 2022-01-22

End date: 2022-04-29

9c. If applicable: indicate which external organization(s) has/have commissioned and/or provided funding for your research.

Commissioning organization(s):

Not applicable

Funding organization(s):

ENTWINE receives funding from the European Union's Horizon 2021-11-30 19:21:18 3/ 6 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 814072.

Grant number:

814072

2. TYPE OF STUDY

Please select the type of study you plan to conduct:

I will be collecting new data from individuals acting as respondents, interviewees, participants or informants.

4. RESEARCH INVOLVING THE COLLECTION OF NEW DATA

A: RESEARCH POPULATION

20. Please provide a brief description of the intended research population(s):

At this stage of the research, professionals in the field of ehealth technologies for caregivers will be interviewed.

21. How many individuals will be involved in your research?

We expect to interview 15 at most 20 individuals

22. Which characteristics must participants/sources possess in order to be included in your research?

There are no specific socio-demographic inclusion criteria for interviewees at this point. However, interviewees will be professionals in the field of eHealth for informal caregivers in Europe.

23. Does this research specifically target minors (<16 years), people with cognitive impairments, people under institutional care (e.g. hospitals, nursing homes, prisons), specific ethnic groups, people in another country or any other special group that may be more vulnerable than the general population?

No

24. Are you planning to recruit participants for your research through the BMS test subject pool, SONA

No

B. METHODS OF DATA COLLECTION

25. What is the best description of your research?

- Interview research

26. Please prove a brief yet sufficiently detailed overview of activities, as you would in the Procedure section of your thesis or paper. Among other things, please provide information about the information given to your research population, the manipulations (if applicable), the measures you use (at construct level), etc. in a way that is understandable for a relative lay person.

At this stage, interviewees will answer open questions about the eHealth technology or innovation their company developed. The

questions will inquire the implementation process and planning, its relevant stakeholders, its wider context, the creative process and value proposition of the innovation. No personal questions or data regarding the individual will be collected except for their contact information and position. The interviewees will receive a copy of the transcription. As a follow up, the interviewees will be asked to check and edit (if necessary) a graphical summary of the interview (following the Business Model Canvas).

How much time will each participant spend (mention the number of sessions/meetings in which they will participate and the time per session/meeting)?

Approximately 45 minutes (each interviewee will take part in one single session) plus a maximum of 15 mins for the asynchronous follow up.

C: BURDEN AND RISKS OF PARTICIPATION

27. Please provide a brief description of these burdens and/or risks and how you plan to minimize them:

No particular risks or burdens are envisioned. The interview will be as brief as possible, on a voluntary participation basis and scheduled at the best convenience of interviewees.

28. Can the participants benefit from the research and/or their participation in any way?

No

29. Will the study expose the researcher to any risks (e.g. when collecting data in potentially dangerous environments or through dangerous activities, when dealing with sensitive or distressing topics, or when working in a setting that may pose 'lone worker' risks)?

No

D. INFORMED CONSENT

30. Will you inform potential research participants (and/or their legal repsentative(s), in case of non-competent participants) about the aims, activities, burdens and risks of the research before they decide whether to take part in the research?

Yes

Briefly clarify how:

The purpose of the study will be briefly disclosed during the recruitment of the participants (most likely through an introductory email) and deepened through the informed consent and information sheet before the interview.

32. How will you obtain the voluntary, informed consent of the research participants (or their legal repsentatives in case of non-competent participants)?

Signed

33. Will you clearly inform research participants that they can withdraw from the research at any time without explanation/justification?

Yes

Attachment: informed-consent_Multiple Case Study Bastoni_14012022_ML.pdf

34. Are the research participants somehow dependent on or in a subordinate position to the researcher(s) (e.g. students or relatives)?

No

35. Will participants receive any rewards, incentives or payments for participating in the research?

- No

36. In the interest of transparency, it is a good practice to inform participants about what will happen after their participation is completed. How will you inform participants about what will happen after their participation is concluded?

- Participants will receive the researcher's contact details, so that they can contact the researcher if they have questions/would like to know more.
- Participants will receive oral/written information about what the researcher(s) will do with the collected data.
- Participants who indicate they are interested will receive a summary of the research results.
- Other (Please specify):

  Participants will be given a copy of the interview transcript so that they can review it and possibly withdraw information they are not comfortable with sharing. They will be given the choice to just being audio recorded instead of video.

E. CONFIDENTIALITY AND ANONYMITY

37. Does the data collected contain personal identifiable information that can be traced back to specific individuals/organizations?

Yes

38. Will all research data be anonymized before they are stored and analysed?

No

39. Will you make use of audio or video recording?

Yes

- What steps have you taken to ensure safe audio/video data storage?

  Only the researchers involved in the project will have access to recording.

- At what point in the research will tapes/digital recordings/files be destroyed?

  The files will be destroyed right after transcription, which will take place shortly after the interviews have taken place.

5. DATA MANAGEMENT

- I have read the UT Data policy.
- I am aware of my responsibilities for the proper handling of

data, regarding working with personal data, storage of data, sharing and presentation/publication of data.

6. OTHER POTENTIAL ETHICAL ISSUES/CONFLICTS OF INTEREST

40. Do you anticipate any other ethical issues/conflicts of interest in your research project that have not been previously noted in this application? Please state any issues and explain how you propose to deal with them. Additionally, if known indicate the purpose your results have (i.e. the results are used for e.g. policy, management, strategic or societal purposes).

No other ethical issues are invisioned

7. ATTACHMENTS

informed-consent_Multiple Case Study Bastoni_14012022_ML.pdf

8. COMMENTS

-

9. CONCLUSION

Status: Approved by commission

The BMS ethical committee / Domain Humanities & Social Sciences has assessed the ethical aspects of your research project. On the basis of the information you provided, the committee does not have any ethical concerns regarding this research project. It is your responsibility to ensure that the research is carried out in line with the information provided in the application you submitted for ethical review. If you make changes to the proposal that affect the approach to research on humans, you must resubmit the changed project or grant agreement to the ethical committee with these changes highlighted.

Moreover, novel ethical issues may emerge while carrying out your research. It is important that you re-consider and discuss the ethical aspects and implications of your research regularly, and that you proceed as a responsible scientist.

Finally, your research is subject to regulations such as the EU General Data Protection Regulation (GDPR), the Code of Conduct for the use of personal data in Scientific Research by VSNU (the Association of Universities in the Netherlands), further codes of conduct that are applicable in your field, and the obligation to report a security incident (data breach or otherwise) at the UT.

Informed consent form template for research with human participants

Dear Participant
Thank you for your permission to be interviewed.

This research is being conducted by Sofia Bastoni from the University of Twente, as part of the ENTWINE ITN Consortium (https://entwine-itn.eu).

The purpose of this interview is to understand how eHealth innovations and technologies to support Informal Care are successfully implemented in practice. Think about how implementation was handled within your organization, what was needed for the implementation of your innovation, what stage of implementation does your innovation find itself in, who are your key stakeholders, how the technology was conceived and how does your context operate. We are interested in your professional opinion and findings, therefore there are no right or wrong answers. In connection with the duration of this assignment, we also wanted to ask if you are available for a short follow up (via email). The interview will last approximately 45 minutes, but you have the right to stop the interview at any time and without giving any explanation.

For the sake of processing this interview, we want to record the meeting. If you are not comfortable with video recordings, you can turn off your camera at any point. With those recording(s) we can transcribe and quote the interview. All names, places and dates will be made anonymous. The recordings are stored securely according to the UT data management system for transcription of the interview. After the transcriptions, the recording will be destroyed. Some of the information or experience you wish to share may be confidential and you do not want it to be used for research purposes. If you do not want us to share certain information you can let us know so that we can handle it discreetly. The anonymized transcript will be shared with you once completed and you can also indicate that we cannot use certain information later.

This research project has been reviewed and approved by the BMS Ethics Committee and no specific risks are envisioned with the participation to this study. Ethical procedures for scientific research, conducted by the Ethics Committee of the Faculty of Behavioral, Management and Social Sciences (BMS) of the University of Twente, require that the interviewees explicitly agree to the interview and how the information will be used in their interviews. This content form is necessary for us to ensure that you understand the purpose of your involvement and that you agree to the terms of your participation.

Therefore, please read the attached consent form and then sign this form to confirm that you agree to the following

UNIVERSITY OF TWENTE.

Consent Form for Successfully implemented technologies to support informal care: multiple case study

YOU WILL BE GIVEN A COPY OF THIS INFORMED CONSENT FORM

Please tick the appropriate boxes

Taking part in the study	**Yes**	**No**
I have read and understood the study information dated [DD/MM/YYYY], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	○	○
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time without having to provide a reason.	○	○
I understand that taking part in the study involves participating to a video recorded online interview for the duration of 45 minutes approximately and a short follow up in the form of email exchange. The recordings will be transcribed and deleted right after. I will receive the transcription and will have the possibility to retract any information that I am not comfortable with sharing.	○	○
Use of the information in the study		
I understand that information I provide will be used for scientific publication purposes. The interview(s) will be analysed, and the result will be reported to describe the implementation of eHealth solutions to support informal care. Furthermore, the publication will be part of the researchers' doctoral dissertation. No other use is envisioned for the data.	○	○
I understand that personal information collected about me that can identify me, such as [e.g., my name or where I live], will not be shared beyond the study team.	○	○
I agree that my information can be quoted in research outputs.	○	○
I agree that my company name can be used for quotes.	○	○
	○	○
Future use and reuse of the information by others		
I give the researchers permission to keep my contact information and to contact me for future research projects.	○	○

Signatures

_____ _____ _____

Name of participant [printed] Signature Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

_____ _____ _____

Researcher name [printed] Signature Date

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Study contact details for further information: Sofia Bastoni, University of Twente Drienerlolaan 5, 7522 NB, Enschede, The Netherlands. Email: s.bastoni@utwente.nl Phone: +31 53 489 5284)

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the Secretary of the Ethics Committee of the Faculty of Behavioural, Management and Social Sciences at the University of Twente by ethicscommittee-bms@utwente.nl

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